

Application No.: 10/612,631
Amdt dated: August 1, 2006
Reply to Office action of May 4, 2006

REMARKS/ARGUMENTS

This Amendment is in response to the Office action of May 4, 2006. Claims 14-21 have been canceled without prejudice to filing a divisional/continuation application with these claims. New claims 22-29 have been added. Claims 1-13 and 22-29 are pending in the application.

Election/Restriction

On page 2 of the action, the action indicates that a provisional election was made without traverse to prosecute the invention of Species 1 directed to Figures 2-17 and Claims 1-13 and requests affirmation of this election. Applicant hereby affirms the election of Species 1 directed to Figures 2-17 and claims 1-13 as readable on the elected species. It was further understood that at least one other species, Species 2, is directed to Figures 18-22 and claims 14-21. Applicant requests confirmation of the restriction requirement as to at least Species 2.

Claims 14-21 have been canceled without prejudice to filing a divisional/continuation application with these claims.

Specification

Also on page 2 of the action, the abstract is objected to because it exceeds 150 words. The abstract has been amended to be less than 150 words. Accordingly, reconsideration and withdrawal of the objection are respectfully requested. The disclosure is also objected to in that on page 8, line 19, it reads, "there is shown a perspective" and should be changed to -- there is a perspective --. Accordingly, the written description on page 8, line 19 has been updated as suggested and thus reconsideration and withdrawal of the objection are respectfully requested.

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Claim Rejections – 35 USC §103

On page 3 of the action, claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Toso et al. (U.S. Patent No 5,282,832), hereinafter “Toso”, in view of Bonutti et al. (U.S. Publication No. 20050267534), hereinafter “Bonutti”. On page 5 of the action, claims 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Toso and Bonutti as applied to Claim 1 and further in view of Wenstrom, Jr. et al. (U.S. Patent No. 6,045,573), hereinafter “Wenstrom”. Applicant respectfully traverses these rejections.

Claim 1 recites that each of said interlocking members has at least one protrusion, at least one mating hole, a standing portion and a mating window. The action only indicates that Toso “discloses the first interlocking member 110 having a “standing portion” consisting of 112 and 113 that engages with “mating window” 121 disposed in the second interlocking member 120.” However, the action and Toso are silent as to the claim elements of at least one protrusion and at least one mating hole as recited in claim 1. As such, the action and Toso confirm that Toso does not teach or suggest all the claim elements recited in claim 1. Thus, a prima facie case of obviousness is not established. Reconsideration and withdrawal of the rejection are therefore respectfully requested.

The action next indicates that Toso “does not disclose the limitations of at least one protrusion, at least one mating well, a standing portion and a mating window for each of the interlocking members”, but again fails to describe or suggest where and how Toso describes or suggests at least one protrusion and at least one mating hole. The action however next indicates that it “would have been obvious to one of ordinary skill in the art to provide these limitations on each of the two interlocking members of the device of Toso et al. for secure engagement of the two connecting elements.”

However, without Toso describing or suggesting at least one member, either first member 110 or retaining member 120, having all the elements of at least one protrusion, at least one mating hole, a standing portion and a mating window, Toso

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does not provide any teaching, suggestion or motivation to modify itself to provide just one member having all four elements recited in claim 1 or even two members. At most, Toso only describes one out of four elements on either first member 110 or retaining member 120. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure (see *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991)). Thus, a *prima facie* case of obviousness is not established and hence reconsideration and withdrawal of the rejection are respectfully requested.

Claim 1 also recites, "a second position for guiding and aligning the suture ends to a preferred location along a tortuous path within and between the first and second interlocking members." Toso, however, at most describes, in col. 3, lines 44-53, the "suture clip first and second members, 110 and 120, are initially separated. One or more suture threadlines 130 are positioned transversely over and across the legs 112 and 113 as shown in FIG. 1. Next the first and second members are moved towards each other, the legs 112 and 113 being inserted into aperture 121 until snap fit engagement is completed and the first and second members 110 and 120 are locked together." As such, Toso at most describes or suggests the first and second members initially separated to position the suture threadlines and next moving the members towards each other until a snap fit engagement is completed locking the members together. Therefore, Toso does not describe or suggest all the claim elements, e.g., a second position, as recited in claim 1. Thus, a *prima facie* case of obviousness is not established and hence reconsideration and withdrawal of the rejection are respectfully requested.

Bonutti also does not cure the above-noted deficiencies of Toso as Bonutti also does not describe or suggest at least one interlocking member having all the elements, i.e., at least one protrusion, at least one mating hole, a standing portion and a mating window, or even interlocking members. The action appears to confirm this by appearing to address only claim 2 with Bonutti indicating that "also not claimed in Toso

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et al. is the protrusions being cylindrical and sized to match opposing mating holes. Bonutti et al. discloses a suture retainer with cylindrical protrusions 360, 362, 364 and 366, which are fixedly connected with rectangular end walls.”

The action also indicates that it “would have been obvious to one of ordinary skill in the art at the time of invention to provide cylindrical protrusions, as taught by Bonutti et al., to the device of Toso et al., in order to form bends lacking stress inducing discontinuities.” However, Toso, in col. 2, lines 35-40, describes that the “flexure of the two legs will accommodate a range of suture sizes to be retained. When the suture is placed in tension, friction is developed at each of the multiple bends that the suture has been subjected to resulting in substantially higher retentive forces.” As such, Toso describes that friction is developed at each of the multiple bends of the suture resulting in substantially higher retentive force while conversely Bonutti describes smooth, continuous bends in the sections 66 and 68 of the suture 52 are free of stress inducing discontinuities. Thus, neither Toso nor Bonutti provide any teaching, suggestion or motivation to make the claimed combination, especially since the references provide contradictory teachings.

The action further indicates that although “opposing mating holes are not located opposite the cylindrical protrusion in Bonutti et al., but rather fixed connections to opposite end walls, it would have been obvious to one of ordinary skill to provide an opposing mating hole to the protrusions since it was known in the art that protrusions of one member readily engage with holes or apertures of another member within two connecting members.” However, without Toso or Bonutti describing or suggesting at least one mating hole, neither Toso nor Bonutti provide any motivation to modify Toso with Bonutti to produce the claimed invention as recited in claim 1. Also, it is contradictory to discard the teaching of Bonutti of fixedly connecting the cylinders to the end walls of a housing enclosing the cylinders to a non-fixed connection and a non-enclosed housing of Toso’s two separable members. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both

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be found in the prior art, not in applicant's disclosure. (see *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991)). Thus, a prima facie case of obviousness is not established and hence reconsideration and withdrawal of the rejection are respectfully requested.

Since claims 2-13 depend from independent claim 1 and thus incorporate the features recited in claim 1 and contain additional limitations that, when considered as a whole are patentably distinguishable over the references of record, claims 2-13 are believed to be patentable. Also, regarding claim 3, the action indicates that "Toso et al. discloses the standing portion consisting of 112 and 113, which could also be considered as protrusion elements, that have barbs 115 and 116 to engage the mating window, which could also be considered as a mating hole (Figure 2)." However, the action and Toso are silent as to how and why the legs 112 and 113 of Toso could also be considered as the two separate elements of a "standing portion" and "at least one protrusion" as recited in claim 3 incorporating claim 1. Likewise, the action and Toso are silent as to how and why the lengthwise extending aperture 121 of Toso could also be considered as the two separate elements of a "mating window" and "at least one mating hole" as recited in claim 3 incorporating claim 1. Thus, since the cited references, alone or combined, do not teach or suggest all the claim elements, a prima facie case of obviousness is not established. Reconsideration and withdrawal of the rejection are therefore respectfully requested.

Regarding claim 6, the action indicates that "Toso et al. lacks the limitation of the assembly of the interlocking members being able to be advanced, retracted or adjusted along the length of the suture." However, Toso does more than not teach the claimed feature, as stated in col. 3, lines 56-58, once "the suture clip 100 is assembled, the suture 130 is securely held in serpentine configuration as shown in FIG. 3." This is in contrast to the assembly of the interlocking members that may be advanced, retracted

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or adjusted along the length of the suture as recited in claim 6. Allowing the Toso's assembly of member 110 and 120 to be advanced, retracted or adjusted would contradict Toso's teachings and make Toso's device inoperable.

The action also indicates that Bonutti et al. discloses the suture retainer being able to move along sections of a suture (page 12, paragraph 161). However, the action, Toso and Bonutti do not provide any teaching, suggestion or motivation to modify Toso's assembly of members 110 and 120 to be a suture retainer of Bonutti that may be advanced, retracted or adjusted. Furthermore, as noted above, modifying Toso's assembly of members 110 and 120 to be advanced, retracted or adjusted would contradict Toso's teachings and make Toso's assembly inoperable. Thus, neither Toso nor Bonutti provide any teaching, suggestion or motivation to make the claimed combination, especially since the references provide contradictory teachings. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. (see *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991)). Thus, a prima facie case of obviousness is not established and hence reconsideration and withdrawal of the rejection are respectfully requested.

Regarding claims 12-13, claim 12 recites, "the metal is malleable" and claim 13 recites, "the interlocking members are formed of plastic and metal." However, the action referring to claims 10-13 indicates that "Toso et al. and Bonutti et al. disclose the claimed device except for the interlocking members being formed of metal, including stainless steel, titanium, silver, gold, and aluminum. Both references also disclose the claimed device except for the metal being malleable and the interlocking members being formed of plastic and metal." Even if Toso and Bonutti do describe the claimed device, which Applicant still disagrees as previously indicated, Wenstrom does not describe or suggest the features recited in claim 12-13. In particular, the action states "Wenstrom, Jr. et al. discloses a suture anchor, or a member having a suture mounted

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thereto, ...". However, Wenstrom's suture anchor is a suture anchor for attaching soft tissue to bone (see Abstract). As such, Wenstrom describes, in col. 4., lines 57-61, that a surgeon locates the surface 701 of the bone 700 and pushes the distal point 50 of the anchor 10 into the cortex 702 of the bone 700 as he begins to rotate the anchor member by rotating the tool 200. Wenstrom's suture anchor being metal that is malleable would make the anchor inoperable having to push into the cortex of the bone as the anchor is rotated. As such, Wenstrom does not provide any teaching, suggestion or motivation to modify Toso, Bonutti or itself to provide malleable metal as provided in claim 12. Wenstrom is also silent like Toso and Bonutti as to any teaching, suggestion or motivation to provide the interlocking member formed of plastic and metal as provided in claim 13.

The action indicates that "one skilled in the art would use well-known materials, such as any suitable metal or non-metal material (plastic), or combination there of, to form the interlocking members in the combined device of Toso et al. and Bonutti et al. since they would yield well-known properties such as being bio-absorbable or malleable, which is helpful in accommodating movement and is bendable." However, based on the teachings of Wenstrom such use of "well-known" materials to be bio-absorbable or malleable would not be desired and thus not taught or suggested as Wenstrom states that the suture anchors may be made constructed from materials that may be "non-absorbable materials" (see col. 3, lines 23-25) and the anchor being able to push and emplaced into bone (see col. 4, line 50 – col. 5, line 4).

Since Toso and Bonutti do not describe any metal or a combination of metal and plastic, as noted in the action, neither Toso and Bonutti provide any teachings, suggestion or motivation to provide malleable metal as provided in claim 12 or the interlocking members formed of plastic and metal as provided in claim 13. Thus, a *prima facie* case of obviousness is not established and reconsideration and withdrawal of the rejection are therefore respectfully requested.

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New claims 22-25 describe other aspects of the invention. For example, new claims 22 and 23 recite that the barbs or increased end diameters of the at least one protrusion and the locking or latching features of the standing portions are in a non-contacting relationship with the suture. New claim 24 recites that the standing portions of one of the first interlocking member and the second interlocking member are extendable through the mating window of one of the first interlocking member and the second interlocking member and foldable onto an exterior surface of one of the first interlocking member and the second interlocking member away from the suture. New claim 25 recites that the first interlocking member has a first length and a first width and the second interlocking member has a second length and a second width, the second length corresponding to the first length and the second width corresponding to the first width. The cited references do not describe or suggest such an apparatus with the recited features in new claims 22-25.

Also, since claims 22-25 depend from an associated independent claim 1 and thus incorporate the features recited in corresponding claim and contain additional limitations that, when considered as a whole are patentably distinguishable over the references of record, claims 22-25 are believed to be patentable.

New claims 26-27 describe other aspects of the present invention. For example, new independent claim 26 also provides a first and second interlocking member with a protrusion, a mating hole, a standing portion and a mating window. Claim 26 also further provides that the first interlocking member has a base in which the protrusion extends from a periphery of the base; the standing portion extends from the base adjacent to the protrusion with the protrusion being substantially smaller than the standing portion. A mating window and a mating hole are also provided both disposed through the base, with the mating window adjacent to the standing portion and the mating hole being substantially smaller and adjacent to the mating window. Claim 27 recites that the standing portion of the first interlocking member has a free end with two

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substantially straight portions extending substantially perpendicular to the base with a substantially curved portion connecting the two generally straight portions together. The cited references do not describe or suggest such an apparatus with the recited features in new claims 26-27. Accordingly, claims 26-27 are believed to be patentable.

New claims 28-29 also describe other aspects of the present invention. For example, new independent claim 28 also provides a first and second interlocking member with a protrusion, a mating hole, a standing portion and a mating window. Claim 28 also further provides that the first interlocking member has a base with a length, a width, a first half and a second half with the width being equal or smaller than the length, a first protrusion extending from the first half of the base, a standing portion extending widthwise from the first half of the base adjacent to the first protrusion, a mating window disposed through the second half of the base adjacent to the standing portion and extending widthwise on the second half of the base, and a mating hole disposed through the second half of the base adjacent to the mating window with the mating hole being substantially smaller than the mating window. Claim 29 recites that the standing portion of the first interlocking member has a width being equal to or greater than the length of the standing portion of the first interlocking member that is less than the length of the base of the first interlocking member. The cited references do not describe or suggest such an apparatus with the recited features in new claims 28-29. Accordingly, claims 28-29 are believed to be patentable.

Applicant also notes that claimed features recited, e.g., the standing portions, the mating window, the protrusion, the mating hole, and the first and second interlocking members, in new claims 22-29 are shown for example in Figures 2-17 of the elected species. Accordingly, new claims 22-29 are believed readable on the elected species.

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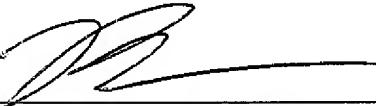
Conclusion

In view of the foregoing remarks, it is respectfully submitted that this application is in condition for allowance. Accordingly, reconsideration of the application and allowance of claims 1-13 and 22-29 are respectfully requested. If the Examiner should have any remaining questions or objections, a telephone interview to discuss and resolve these issues is respectfully requested.

Sincerely

APPLIED MEDICAL RESOURCES

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